K082620

# 510(k) Summary

**Submitted by** Propper Manufacturing Company, Inc.
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Long Island City, New York 11101
**Telephone:** (800) 832-4300 or (718) 392-6650
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**Contact Name:** Marian M. Schuman, Executive V.P. / General Counsel

JUL - 8 2009

**Date Submitted:** September 8, 2008

**Trade Name:** Once-A-Day® Vertos™ Test Pack
**Common Name:** Chemical Sterilization Process Indicator (Bowie & Dick Test Pack)

**Product Code / Regulation:** JOJ / 21 C.F.R. 880.2800

**Description:** The Once-A-Day® Vertos™ Test Pack is a Bowie & Dick type test for pre-vacuum steam sterilizers that complies with requirements of AAMI/ANSI/ISO 11140-1:2005 as class 2 indicator, which includes conformance with the labeling requirements and general requirements on the performance. The pack also complies with requirements of AAMI/ANSI/ISO 11140-5:2007, which includes the test format parameters, performance at 134° C for 3.5 min in Pass and Fail cycles, dry heat test parameters, ink transfer limitations, labeling requirements, and all normative described in annexes.

**Intended Use:** The Once-A-Day® Vertos™ Test Pack is an air removal indicator that is intended to be used by a health care provider as a standardized test pack, e.g., Bowie Dick Test Pack, to assess the ability of a pre-vacuum sterilizer to remove air and allow steam to penetrate into wrapped goods and porous loads operating at 134° C using a 3.5 minutes exposure time. The Once-A-Day® Vertos™ Test Pack is directed to be positioned on the lowest shelf over the chamber drain in an otherwise empty chamber. An inefficient air removal stage, an air leak, or non-condensable gases in the steam supply are some of the conditions that could cause an incomplete change in the air removal indicator, e.g., uneven color change. An unexposed test pattern is uniformly blue and a uniform pink test pattern represents an acceptable cycle. The Once-A-Day® Vertos™ Test Pack is not an indication that the sterilizer has reached the parameters for sterilization.

**Substantial Equivalence:** The Once-A-Day® Vertos™ Test Pack is similar in intended use and operating characteristics to Propper's once-a-day® Bowie and Dick Test Pack, K961156. Substantial equivalence to the predicate

device was evaluated according to the FDA guidance document "Premarket Notification [510(k)] Submissions for Chemical Indicators," issued on December 19, 2003.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marian M. Schuman
Executive Vice President/General Counsel
Propper Manufacturing Company, Incorporated
36-04 Skillman Avenue
Long Island City, New York 11101

JUL - 8 2009

Re: K082620
Trade/Device Name: Once-A-Day® Vertos™ Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: June 12, 2009
Received: June 16, 2009

Dear Ms. Schuman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Enclosure

# Indications for Use

**510(k) Number (if known):** K082620

**Device Name:** Once-A-Day® Vertos™ Test Pack

**Intended Use:**

The Once-A-Day® Vertos™ Test Pack is an air removal indicator that is intended to be used by a health care provider as a standardized test pack, e.g., Bowie Dick Test Pack, to assess the ability of a pre-vacuum sterilizer to remove air and allow steam to penetrate into wrapped goods and porous loads operating at 134° C using a 3.5 minutes exposure time. The Once-A-Day® Vertos™ Test Pack is directed to be positioned on the lowest shelf over the chamber drain in an otherwise empty chamber. An unexposed test pattern is uniformly blue and a uniform pink test pattern represents an acceptable cycle. The Once-A-Day® Vertos™ Test Pack is not an indication that the sterilizer has reached the parameters for sterilization.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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